Express Mail No.: EV977390134US

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Pettis et al. Confirmation No.: 3767

Application No.: 09/606,909 Group Art Unit: 7814

Filed: June 29, 2000 Examiner: Hayes, Michael J.

For: INTRADERMAL DELIVERY OF Attorney Docket No.: 11219-008-999

**SUBSTANCES** 

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.56 AND §1.97

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 and §1.97 to inform the United States Patent and Trademark Office ("USPTO") of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby invite the Examiner's attention to references A01-A18, B01-B02, and C01-C13 listed on the attached form entitled "List of References Cited by Applicant."

Copies of references B01-B02 and C01-C13 are submitted herewith. Copies of references A01-A18 are not submitted herewith because they are U.S. patents or U.S. patent application publications. Pursuant to 37 C.F.R. § 1.98 (a)(2)(i) as amended (*see* Fed. Reg. vol. 69, no. 182, Sept. 21, 2004), the requirement for providing a copy of each U.S. patent or U.S. patent application publication listed in an Information Disclosure Statement in a patent application, regardless of the filing date of the application, is eliminated.

Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application.

Applicants respectfully requests that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(c), since this information disclosure statement is being filed after the mailing date of a first Office Action on the merits, a fee of \$180 is believed to

be due in connection herewith. Please charge the required fee to Jones Day deposit account no. 50-3013. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date:

**JONES DAY** 

222 East 41<sup>st</sup> Street

New York, New York 10017-6702

(212) 326-3939

**Enclosure** 

By: Enic A. Mende Rey. No. 42,876



## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO. 11219-008-999 (500752-999007,	APPLICATION NO.
P-4901)	09/606,909
APPLICANT	
Pettis et al.	
FILING DATE	ART UNIT
June 29, 2000	3767

	U.S. PATENT DOCUMENTS				
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR
INTIAL	A01	5,800,420	09/1998	Gross, et al.	
	A02	6,007,821	12/1999	Srivastava, et al.	
	A03	6,200,291	03/13/2001	Di Pietro	
	A04	6,482,176	11/19/2002	Wich	
	A05	6,537,242	03/2003	Palmer	
<del></del>	A06	US 2002/0095134	07/2002	Pettis, et al.	
	A07	US 2002/0156453	10/24/02	Pettis, et al.	
	A08	US 2003/0100885	5/29/03	Pettis, et al.	
	A09	US 2004/0028707	02/12/2004	Pinkerton	
	A10	US 2004/0073160	04/15/2004	Pinkerton	
·	A11	US 2004/0082934	04/29/04	Pettis, et al.	
	A12	US 2004/0170654	09/02/2004	Pinkerton	
	A13	US 2004/0175360	09/09/04	Pettis, et al.	
	A14	US 2004/0175401	09/09/2004	Pinkerton	
	A15	US 2005/0096330	05/05/2005	Pettis, et al.	
	A16	US 2005/0096331	05/05/2005	Pettis, et al.	
	A17	US 2005/0096332	05/05/2005	Pettis, et al.	
	A18	US 2005/0256499	11/17/05	Pettis, et al.	

FOREIGN PATENT DOCUMENTS						
		FOREIGN PATENT DOCUMENT COUNTRY CODE, NUMBER, KIND CODE (IF KNOWN)	DATE	NAME	PAGES, COLUMNS, LINES, WHERE RELEVANT PASSAGES OR RELEVANT FIGURES APPEAR	Т
	B01	WO 02/083232	10/24/2002	Becton, Dickinson and Company		
	B02	WO 03/002175	01/09/2003	Pharmacia Corporation		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	Т		

<b>EXAMINER</b>
NYI-3909892v1

DATE CONSIDERED

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



## LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO. 11219-008-999 (500752-999007,	APPLICATION NO.
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NON PATENT LITERATURE DOCUMENTS				
Examiner		(T. 1.1. C.) (C.) CAPITALI I ETTERO), Till. D D D D	T	
Initials		(Include name of the author (in CAPITAL LETTERS), Title, Date, Pertinent Pages, Etc.)	T	
	C01	"Flu vaccine: skin injection method effective in younger people," American Health Line: Research Notes (2004 Nov. 4)		
	C02	BELSHE et al., "Serum antibody responses after intradermal vaccination against influenza," New England Journal of Medicine 351(22):2286-2294 (2004)		
	C03	BRANSWELL, "Vaccine stretching may be an option for future shortages, pandemics: studies," Canadian Press News Wire (2004 Nov. 3)		
	C04	FJERSTAD, "U. Minnesota professor uses alternative flu vaccine technique," FSView & Florida Flambeau via U-Wire (2004 Nov. 15)		
	C05	KENNEY et al., "Dose sparing with intradermal injection of influenza vaccine," New England Journal of Medicine 351(22):2295-2301 (2004)		
	C06	KNOX et al. "New research shows intradermal rather than intramuscular vaccine injection could stretch flu vaccine supplies," National Public Radio: All Things Considered (2004 Nov. 3)		
	C07	KOHN, "Flu shot technique yields more doses, studies find; critics say injecting skin rather than muscle is too difficult for common use," The Baltimore Sun: Telegraph 3A (2004 Nov. 4)		
	C08	MAJESKI et al., "Technique could stretch vaccine; changing the way shots are given means the current supply of flu vaccine could immunize 10 times as many people, two Minnesota physicians say" Saint Paul Pioneer Press: Main 1A (2004 Oct. 27)		
	C09	MAJESKI, "Alternate flu shot less effective in elderly; doctors proposed method to stretch vaccine supply,"  Saint Paul Pioneer Press: Main 17A (2004 Nov. 4)		
	C10	MONTAGNE et al., "Intradermal influenza vaccination - can less be more?" New England Journal of Medicine 351(22):2330-2332 (2004)		
, "	C11	RINDFLEISCH et al., "La Crosse finding could curtail flu vaccine shortages," Wisconsin State Journal D9 (2004 Nov. 14)		
	C12	SHUTE "Second thoughts on the flu vaccine," Science & Society; Public Health 137(17):80	Ī	
	C13	SMITH, "Low-dose vaccine helps block flu, study says younger adults seen benefiting," <i>The Boston Globe:</i> National/Foreign A2 (2004 Nov. 4)		

EXAMINER
EXAMINER NYI-3909892v1

DATE CONSIDERED